

Application No.: 10/643,315  
Applicant(s): Spiridigliozzi, et al.  
Docket No.: 760-100 CIP  
Amendment and Response dated November 22, 2006

## **REMARKS**

### **I. Introduction**

Claims 1 to 47 are pending in this application. Claims 16, 18, 34, 36, and 38 to 47 were previously withdrawn from consideration as being directed to non-elected species/invention. Claims 1 to 15, 17, 19 to 33, 35 and 37 remain rejected by the final Office Action.

By this amendment, Applicants have amended claims 1 and 19 to further and more precisely define the present invention. Further, Applicants have also amended claim 21 to clarify the subject matter being claimed.

### **II. Interview Summary**

Applicants thank the Examiner for the interview held between the Applicants' representative and the Examiner on November 15, 2006.

During the course of the interview, Applicants' representative pointed out the particular features which define the present invention over the prior art of record. In addition, terms of art, "pleat" and "crimp" were referenced in two different dictionaries and their different meanings were discussed. As a result of the discussion, Applicants' representative, with the Examiner's guidance, endeavored to clarify the discussed combination of features and capture them in the claim language. As a result of the discussion, the Examiner suggested that Applicants'

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representative submit a final draft of the amended claims in a response. The Examiner assured the representative that, if the amended claims cannot be entered, the Examiner will contact Applicants' representative with further suggestions and guidance.

It is Applicants' position that the currently amended claims now clearly clarify the combination of features which define over the prior art of record. By this amendment, Applicants have amended several claims to overcome the Examiner's rejections and respectfully makes assertions for overcoming the rejections of the outstanding Office Action needed August 22, 2006 in the following paragraphs.

### **III. Double Patenting**

Claims 1 to 15, 17, 19 to 33, 35 and 37 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 to 3 and 5 to 17 of co-pending Application Number 10/166, 842.

In response, Applicants have taken formal notice of this issue. Upon indication of allowable subject matter, Applicants will consider filing a terminal disclaimer to obviate the judicially created doctrine of obviousness-type double patenting over the claims of co-pending Application Number 10/166,842.

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#### **IV. Claim Rejections -- 35 USC §103**

Claims 1 to 15, 17, 19 to 33, 35 and 37 remain rejected under 35 USC §103 (a) as being unpatentable over the U.S. Pat. No. 4,850,999 to Planck (hereinafter "Planck '999") in view of the U.S. Pat. No. 6,264,684 to Banas (hereinafter "Banas '684"), and in further view of U.S. Pat. No. 5,628,788 to Pinchuk (hereinafter "Pinchuk '788"). This rejection is based on the Office's position that the combination of the references make the present invention as claimed, obvious.

Specifically, the Office Action states that Planck '999 discloses the combination of all features in the present invention as claimed. However, the Office Action admits that Planck '999 failed to disclose the bonding agent, the application of the graft comprising a plurality of longitudinally spaced crimps, or that the bonding agent is applied in a solution of dimethylacetamide. The rejection, then relies on Banas '684 to show the features of the bonding agent and the application of graft comprising a plurality of longitudinally spaced crimps. Furthermore, the rejection relies on Pinchuk '788 to disclose the feature of applying the bonding agent in the form of a solution comprising dimethylacetamide to accelerate the drying time or spray buildup for the polyurethane bonding agent.

It is Applicants' position that claims 1 to 15, 17, 19 to 33, 35, and 37 are patentable over Planck '999 in view of Banas '684 and further in view of Pinchuk '788. The present invention as amended provides for a combination of features not taught by the prior art as a whole including Planck '999, Banas '684, and Pinchuk '788. For instance, there are several differences for the present invention as claimed.

**A. The Pleated Folds are Not Secured to the Textile Material Layer**

Specifically, claim 1 as amended provides at least two additional features. First, the claim 1 as amended now specifies that the portion of the first layer that is pleated to the second layer is not secured thereto. Thus, once the first layer is folded, the adhesive layer is not applied to the overlaying layer underneath the folded portion.

**B. The Textile Material is Disposed Over the Secured Portion as well as the Pleated Portion**

Second, claim 1 also specifies that the second layer is disposed over the secured portions as well as the pleated fold portion.

**C. Banas '684 Reference Differs in at Least Three (3) Features**

Banas '684, which was relied on to show the crimps (which the office equates with pleats) and bonding agent, has at least three (3) major differences from the present invention as claimed. As a result of these differences, Banas '684 can not be relied on to obviate the present invention as claimed. The differences are as follows:

**1. Banas '684 Reference is Helically Wound and Not Pleated**

First, the Office Action relies on the embodiment disclosed by FIG. 13 of Banas '684 to postulate that Banas '684 shows "crimps." However, in contrast to the present invention as claimed, the overlapping seams shown in figure 13 of Banas '684 are formed

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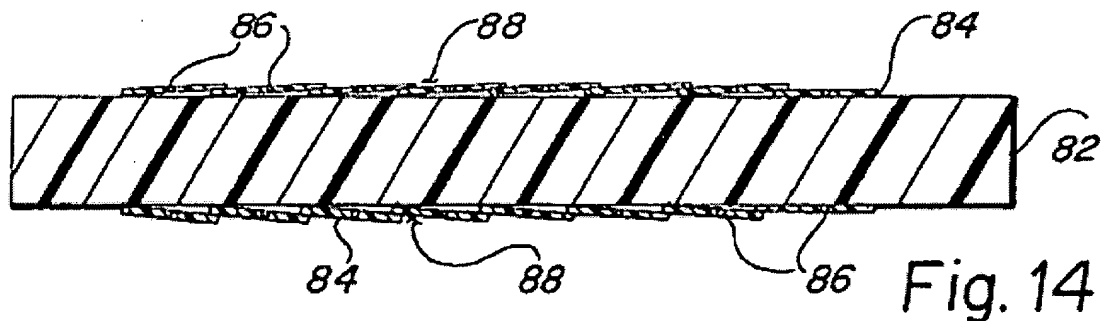
by helically winding the polymer cladding. This is specifically recited in Banas '684 disclosure, wherein it states in column 10, lines 47 to 56 as follows:

"Finally, an alternative embodiment of a shape memory alloy supported intraluminal graft 80 is depicted in figures 13 and 14. The inventive shape memory alloy supported intraluminal graft 80 may be formed by **helically wrapping** a length of polymer clad 84 shape memory alloy wire 86 about a supporting winding mandrel, such that the polymer cladding 84 has overlapping regions 88 which form seams. The resulting assembly is then heated above the melt point of the polymer cladding 84 to **join and seal** the overlapping regions 88 to one another." (emphasis added)

The Banas '684 disclosure makes it clear that its device includes heat sealed seams which result from helically wound wire with polymer around it. This is totally different from the present invention of ePTFE which has pleats along the longitudinal length about its axis, where the overlapping region is not joined as to permit longitudinal extension. To suggest anything other than helically wrapped cladding with joined and sealed seams would make the device of Banas '684 unfeasible. Therefore, Banas ' 684 clearly directs a person of ordinary skill in the art away from the inventive features provided in the claims as amended.

**2. The "Crimps" of the Banas '684 Device are Joined and Sealed to Each Other**

Second, Banas '684 clearly states that the resulting assembly is melted to join and seal the overlapping regions 88 to one another. In contrast, the present invention as amended provides that the pleated folds are not secured to the second layer.



**3. Banas '684 Reference Does Not Suggest a Textile Layer Covering Both Areas**

Furthermore, the present invention as claimed also provides for a second layer that is disposed over the secured portions and the pleated folds. Banas '684 provides for a device which cannot be combined with a second layer that is disposed over the polymer. In fact, Banas '684 does not discuss a textile layer on top because another layer on top of the helically wound device would complicate the function of the device. If the polymer includes a second layer on top, the device will not function as disclosed by Banas ' 684. Therefore, Banas ' 684 can not be combined with Planck ' 999.

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**D. Effects of the Differences in the Present Invention**

The combination of features not taught by the prior art of record provides several improved effect for the present invention as claimed. For instance, the present invention as claimed has the advantage of providing a second layer that is naturally porous, which allows desired tissue ingrowth. Furthermore, a pleated ePTFE graft can overcome the disadvantages of being noncompliant as compared with textile grafts and natural vessels by providing flexibility through its pleated folds.

**E. No Incentive to Combine the References**

Furthermore, Applicants find no incentive in Planck '999, Banas '684, or Pinchuk '788 which would lead a person of ordinary skill in the art to all of the structural features of the present invention, including a first layer and a second layer where the first layer has unsecured pleated folds and the second layer is disposed over the secured portions as well as the pleated folds. Therefore, claim 1 can not be obvious in view of the above references.

There must be some suggestion or teaching in the prior art of the whole which would lead the person of ordinary skill in the art to provide the combination as claimed. When the references are taken for their teachings as a whole, they are devoid of any teaching or guidance which would lead one of ordinary skill in the art to the invention. As the prior art as a whole failed to direct the person of ordinary skill in the art to the claimed combination, the invention should be considered patentable.

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**F. Dependent Claims 2-15 are also Not Obvious**

Claims 2 to 15 depend on claim 1 and include the combination of features provided in claim 1. Thus, the prior art of record also fails to anticipate or suggest the combination of features included in these claims as well. Thus, Applicants respectfully request favorable consideration of these claims as well.

**G. Independent Claim 19**

Claim 19 also sets forth a combination of features which define over the prior art. Specifically, claim 19 recites that each of the committed folds are provided by doubling a continuous portion of the first layer up on itself and pressing the continuous portion into an adjacent portion.

Banas '684 fails to teach or suggest such features. As stated above, the overlapping regions 88 of Banas '684 is made by helical winding of the device. Therefore, the present invention as amended in claim 19 is not suggested by the Banas '684. Further, since there is no suggestion or motivation to combine the references as suggested by the Examiner, Applicants submit that they are not properly combinable. Moreover, the combination of the references fail to arrive at the claims as amended.

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**H. Dependent Claims 20, 33, 35, 37 and 39 are Not Obvious**

Since claims 20 to 33, 35, and 37 depend on claim 19 and also includes the combination of features included in claim 19, the combination of references also cannot suggest these claims as well.

**I. Summary**

As the prior art as a whole fails to suggest the combination of features as claimed, Applicants respectfully request that the Examiner favorably consider the claims as now amended. Applicants respectfully solicit allowance of this application.

Should the Examiner determine that issues remain that have not been resolved by this response, the Examiner is requested to contact Applicants' representative at the number listed below.

Favorable action on the merits is requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'DK', is enclosed within a hand-drawn oval.

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